## REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on May 1, 2008. No fee is due in connection with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-694 on the account statement.

Claims 1-20 are pending in this application. Claims 1-10, 12-13, 15 and 19-20 were previously withdrawn. Claim 14 was previously cancelled. In the Office Action, the specification is objected to. Claims 11 and 17-18 are rejected under 35 U.S.C. § 112. Claims 11 and 17-18 are rejected under 35 U.S.C. § 102. In response, Claims 11 and 17-18 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, the specification has been objected to for the allegedly improper use of the trademarks ARASCO and DHASCO. See, Office Action, page 2, lines 11-18. The Patent Office also asserts that the "cited occurrences of improper use are only exemplary and applicant should review the specification to correct an other use of trademarks." *Id.* In response, Applicants have amended the trademarks ARASCO, DHASCO, Raftiline, Glucidex and Fluka to include the registered trademark designation, ®. Further, since the formerly registered trademark Vivinal is now abandoned, Applicants have amended Vivinal to include the common law trademark designation, ™. To reflect these changes, Applicants have replaced the paragraph at page 13, lines 10-19 that begins "Animals were fed from PND15" to include the designations described above, as is shown in the Amendments to the Specification at page 2 of this Amendment. Similarly, Table 1 has also been amended to include the designations above. As such, Applicants respectfully request the Patent Office to replace Table 1 with the revised Table 1 at page 3 of this Amendment. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

In the Office Action, Claims 11 and 17-18 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, with respect to Claim 11, the Patent Office alleges that Claim 11 is rendered vague and indefinite by the phrase "a combination of at least

one substance selected from the group consisting of specific fats or non-digestible oligosaccharides, associated with a microorganism." See, Office Action, page 2, line 26-page 3, line 1. In response to the Patent Office's concerns, Applicants first note that the word "specific" has been deleted from Claim 11. As such, Applicants respectfully submit that, when read in view of the specification, the skilled artisan would immediately appreciate which fats may be used in accordance with the present claims. For example, and without being limited to the following fats, the specification clearly states that particular fatty acid lipids, gangliosides and milk fractions, for example, may be used. See, specification, page 4, line 24-page 6, line 11. Because several examples of fats are provided in the specification, Applications respectfully submit that the skilled artisan would understand which fats may be used in accordance with the present claims.

Further, Applicants have deleted the term "associated" from Claim 11 and amended Claim 11 to recite that the beneficial ingredients are used in combination with a microorganism. Applicants have also clarified that the scope of Claim 11 relates to the combination of an element of the Markush group (*e.g.*, the beneficial ingredients) with a microorganism. For example, Claim 11 now recites, in part, a combination of a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism. Thus, Applicants respectfully submit that it is now clear that the combination is of at least one of a fat, non-digestible oligosaccharide or combination thereof with at least one microorganism. This amendment has also specified which elements of Claim 11 are included in the Markush group (*e.g.*, fats, non-digestible oligosaccharides or combinations thereof).

With respect to Claim 17, the Patent Office asserts that neither the claims nor the specification provides any means of accomplishing the "step" of " ensuring an optimal barrier function in infants." The Patent Office further states that "the use of the word 'an' implies there are multiple barrier functions and that only one needs to be optimized." See, Office Action, page 3, lines 14-22. In contrast, however, Applicants respectfully submit that the specification describes how, during postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria. This phenomenon is called gut closure and appears to be affected by the newborn's diet. Hence, different studies with infants (JPGN, 1995, 21: 383-6) and animal

models (Pediatr. Res., 1990, 28: 31-7) show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns. This could explain the higher prevalence of allergy and infection in infants fed formula than in those fed with mother milk. See, specification, page 1, lines 13-19. Further, the specification also clearly demonstrates that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. Moreover, the specification also clearly demonstrates, via Example 1, that rats who consumed compositions of the present invention were found to have restored intestinal permeability to normal levels after maternal separation, which increased the intestinal permeability to proteins and other macromolecules. See, specification, page 15, lines 2-4. This Example illustrates how the uses of the compositions of the present invention work to ensure an optimal barrier function in infants (*e.g.*, rat pups). See, specification, Example 1.

Applicants also respectfully submit that the word "an" is placed in front of the phrase "optimal barrier function" not to imply that there are multiple barrier functions, as suggested by the Patent Office, but rather to introduce the optimal barrier function with proper antecedent basis in accordance with U.S. patent procedures.

Regarding Claim 18, the Patent Office alleges that neither the claims nor the specification provides any means of accomplishing the "step" of "reducing the risk of developing allergy and infection." The Patent Office further asserts that by administering microorganisms, "one is inducing infection and it is not clear how this can reduce the risk of developing infection." See, Office Action, page 3, lines 23-27. However, Applicants respectfully disagree with the Patent Office's assertions. For example, as discussed above, the specification clearly describes the importance of an infant to be exposed to certain bacteria and/or macromolecules contained in the milk of its mother during postnatal development. The bacteria and/or macromolecules in the mother's milk aid in the phenomenon of gut closure, wherein the infant's gut establishes a functional barrier to macromolecules and pathogenic bacteria. In contrast, when the infant is not exposed to the bacteria and/or macromolecules of the mother's milk, studies have shown that these infants will be more susceptible to allergy and infection because the infants' gut will not block the macromolecules and/or pathogenic bacteria as well. See, specification, page 1, lines

13-19. As such, and in contrast to the Patent Office's assertion, exposing infants to the microorganisms during postnatal development will reduce the risk of developing allergy and infection. Therefore, in view of the amendments and/or for at least the reasons set forth above, Applicants respectfully submit that the skilled artisan would immediately understand the scope of amended Claims 11 and 17-18 when read in view of the specification.

Based on at least these noted reasons, Applicants believe that Claims 11 and 17-18 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 11 and 17-18 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 11 and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 01/64225 to Haschke et al. ("*Haschke*") and by WO 03/041512 to Giffard et al. ("*Giffard*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claim 11 recites a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising the steps of administering a combination of a least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof, and at least one microorganism, to an infant inducing a pattern of gut barrier maturation similar to that observed with breast-feeding. During postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria (*i.e.*, gut closure). Different studies with infants and animal models show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns, and could aid in explaining the higher prevalence of allergy and infection in infants fed formula than in those fed with mother milk. See, specification, page 1, lines 13-19.

An impressive number of different mechanisms integrate this barrier, mechanisms that act synergistically to protect the host from the luminal aggressions. The first barrier consists on the intestinal epithelium, a continuous monolayer of columnar epithelial cells sealed together by protein complexes, such as the tight junctions. The second is a non-specific barrier composed by mechanisms that protect the mucosal surface as saliva, gastric acidity, mucus layer, proteolytic digestion, alkaline intestinal pH, unstirred layer and intestinal peristalsis. The gut immune

system (GALT) is able to respond selectively and specifically to the foreign molecules and pathogen microorganisms. Finally, and not less important, intestinal flora directly and indirectly protect against host invasion by pathogens and macromolecules with antigenic properties. See, specification, page 1, line 21-page 2, line 4.

In accordance with the present claims, Applicants have surprisingly found that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. The microorganisms of the present claims, which differ in their ability to survive in the different parts of the gastro-intestinal tract, can be incorporated into a cocktail. Thus, the bioactive ingredients can be added to the microorganism cocktail in order to reinforce their effects by stimulating the maturation of barrier mechanisms different to those stimulated by the microorganisms. See, specification, page 3, lines 11-17. The microorganisms of the present invention are designed to release the specific bioactive ingredients at a certain desired location of the gut and may be administered to a recipient, whereupon they will lyse at the respective location in the gut depending on the sort of pretreatment undergone by the microorganism. See, specification, page 7, lines 11-28. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every limitation of the present claims.

For example, *Hascke* and *Giffard* each fail to disclose or suggest a method comprising the step of administering a composition to an infant inducing a pattern of gut barrier maturation similar to that observed in breast-feeding. In fact, neither reference recognizes or even suggests the applicability of their compositions to an infant to induce a pattern of gut barrier maturation. Moreover, neither reference compares the effects of their compositions to those observed with breastfeeding.

As discussed above, Applicants have surprisingly found that gut barrier function or gastrointestinal health in infants may be improved by providing the specific bioactive ingredients of the present claims combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See, specification, page 3, lines 2-5. The bioactive ingredients can be added to the microorganisms in order to reinforce their effects by stimulating the maturation of barrier mechanisms different to those stimulated by the microorganisms. See,

specification, page 3, lines 11-17. The examples in the specification reinforce this by showing that a combination of functional ingredients such as, for example, long chain polyunsaturated fatty acids (LC-PUFA), oligosaccharides and lactobacillus restores intestinal permeability to normal levels after maternal separation. See, specification, page 16, [0079]. Therefore, the combination of the specific claimed bioactive ingredients and at least one microorganism recited in the present claims provides a specific effect not taught or suggested by the cited references.

Moreover, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. In the case of the cited references, each fails to disclose or suggest a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising the steps of administering a composition, to an infant inducing a pattern of gut barrier maturation similar to that observed with breast-feeding. For at least these reasons, Applicants respectfully submit that the cited references fail to anticipate the presently claimed subject matter.

Accordingly, Applicants respectfully request that the rejection of Claims 11 and 17-18 under 35 U.S.C. §102 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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